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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,905	TANG ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-93 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-93 are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1-93 are pending in the application.

[2] The specification is objected to as applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Lack of Unity

[3] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or goups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Groups I-XIII, claims 1-2, 9, 16-18, 30-42, and 56-68, drawn to the special technical feature of an isolated polypeptide, the first claimed method of making, a composition comprising a polypeptide, and the first claimed method of use, i.e., a method of using a composition comprising a polypeptide for treating a disease. Group I recites SEQ ID NO:1, Group II recites SEQ ID NO:2, Group III recites SEQ ID NO:4,... ...and Group XIII recites SEQ ID NO:14.

Groups XIV-XXVI, claims 3-7, 11-12, 43-55, 85, and 87-93, drawn to the special technical feature of an isolated polynucleotide, a recombinant polynucleotide, a cell, an array, and a microarray. Group XIV recites a nucleic acid encoding SEQ ID NO:1 including SEQ ID NO:16, Group XV recites a nucleic acid encoding SEQ ID NO:2 including the nucleic acid of SEQ ID NO:17, Group XVI recites a nucleic acid encoding SEQ ID NO:4 including SEQ ID NO:19,... ...and Group XXVI recites a nucleic acid encoding SEQ ID NO:29 including SEQ ID NO:14.

Groups XXVII-XXXIX, claim 8, drawn to the special technical feature of a transgenic organism. Group XXVII recites a transgenic organism comprising a nucleic acid encoding SEQ ID NO:1 including SEQ ID NO:16, Group XXVIII recites a transgenic organism comprising a nucleic acid encoding SEQ ID NO:2 including SEQ ID NO:17, Group XXIX recites a transgenic organism comprising a nucleic acid encoding SEQ ID NO:4 including SEQ ID NO:19,... ...and Group XXXIX recites a transgenic organism comprising a nucleic acid encoding SEQ ID NO:29 including SEQ ID NO:14.

Groups XL-LII, claims 10, 70-71, 73, and 75-82, drawn to the special technical feature of an isolated antibody that binds a polypeptide, a composition thereof, and methods for preparing an antibody. Group XL recites SEQ ID NO:1, Group XLI recites SEQ ID NO:2, Group XLII recites SEQ ID NO:4,... ...and Group LII recites SEQ ID NO:14.

Groups LIII-LXV, claims 13-15, drawn to the special technical feature of a method of detecting a target polynucleotide. Group LIII recites the nucleic acid of SEQ ID NO:16, Group LIV recites the nucleic acid of SEQ ID NO:17, Group LV recites the nucleic acid of SEQ ID NO:19,... ...and Group LXV recites the nucleic acid of SEQ ID NO:29.

Groups LXVI-LXXVIII, claim 19, drawn to the special technical feature of a method for screening a compound for effectiveness as an agonist of a polypeptide. Group LXVI recites SEQ ID NO:1, Group LXVII recites SEQ ID NO:2, Group LXVIII recites SEQ ID NO:4,... ...and Group LXXVIII recites SEQ ID NO:14.

Groups LXXIX-XCI, claim 20, drawn to the special technical feature of a composition comprising an agonist compound. Group LXXIX recites SEQ ID NO:1, Group LXXX recites SEQ ID NO:2, Group LXXXI recites SEQ ID NO:4,... ...and Group XCI recites SEQ ID NO:14.

Groups XCII-CIV, claim 21, drawn to the special technical feature of a method for treating a disease by administering a composition comprising an agonist compound. Group XCII recites SEQ ID NO:1, Group XCIII recites SEQ ID NO:2, Group XCIV recites SEQ ID NO:4,... ...and Group CIV recites SEQ ID NO:14.

Groups CV-CXVII, claim 22, drawn to the special technical feature of a method for screening a compound for effectiveness as an antagonist of a polypeptide. Group CV recites SEQ ID NO:1, Group CVI recites SEQ ID NO:2, Group CVII recites SEQ ID NO:4,... ...and Group CXVII recites SEQ ID NO:14.

Groups CXVIII-CXXX, claim 23, drawn to the special technical feature of a composition comprising an antagonist compound. Group CXVIII recites SEQ ID NO:1, Group CXIX recites SEQ ID NO:2, Group CXX recites SEQ ID NO:4,... ...and Group CXXX recites SEQ ID NO:14.

Groups CXXXI-CXLIII, claim 24, drawn to the special technical feature of a method for treating a disease by administering a composition comprising an antagonist compound. Group CXXXI recites SEQ ID NO:1, Group CXXXII recites SEQ ID NO:2, Group CXXXIII recites SEQ ID NO:4,... ...and Group CXLIII recites SEQ ID NO:14.

Groups CXLIV-CLVI, claims 25-26, drawn to the special technical feature of a method of screening a compound that specifically binds to or modulates the activity of a polypeptide. Group CXLIV recites SEQ ID NO:1, Group CXLV recites SEQ ID NO:2, Group CXLVI recites SEQ ID NO:4,... ...and Group CLVI recites SEQ ID NO:14.

Groups CLVII-CLXIX, claims 27 and 29, drawn to the special technical feature of a method of screening a compound for effectiveness in altering expression of a polynucleotide. Group CLVII recites the nucleic acid of SEQ ID NO:16, Group CLVIII recites the nucleic acid of SEQ ID NO:17, Group CLIX recites the nucleic acid of SEQ ID NO:19,... ...and Group CLXIX recites the nucleic acid of SEQ ID NO:29.

Groups CLXX-CLXXXII, claim 28, drawn to the special technical feature of a method for assessing toxicity of test compound. Group CLXX recites the nucleic acid of SEQ ID NO:16, Group CLXXI recites the nucleic acid of SEQ ID NO:17, Group CLXXII recites the nucleic acid of SEQ ID NO:19,... ...and Group CLXXXII recites the nucleic acid of SEQ ID NO:29.

Groups CLXXXIII-CXCV, claims 69, 72, and 74, drawn to the special technical feature of a diagnostic test and a method of diagnosing a condition or disease, Group CLXXXIII recites the nucleic acid of SEQ ID NO:16, Group CLXXXIV recites the nucleic acid of SEQ ID NO:17, Group CLXXXV recites the nucleic acid of SEQ ID NO:19,... ...and Group CXCV recites the nucleic acid of SEQ ID NO:29.

Groups CXCVI-CCVIII, claim 83, drawn to the special technical feature of a method for detecting a polypeptide. Group CXCVI recites SEQ ID NO:1, Group CXCVII recites SEQ ID NO:2, Group CXCVIII recites SEQ ID NO:4,... ...and Group CCVIII recites SEQ ID NO:14.

Groups CCIX-CCXXI, claim 84, drawn to the special technical feature of a method of purifying a polypeptide. Group CCIX recites SEQ ID NO:1, Group CCX recites SEQ ID NO:2, Group CCXI recites SEQ ID NO:4,... ...and Group CCXXI recites SEQ ID NO:14.

Groups CCXXII-CCXXXIV, claim 86, drawn to the special technical feature of a method of generating a transcript image of a sample containing polynucleotides. Group CCXXII recites the nucleic acid of SEQ ID NO:16, Group CCXXIII recites the nucleic acid of SEQ ID NO:17, Group CCXXIV recites the nucleic acid of SEQ ID NO:19,... ...and Group CCXXXIV recites the nucleic acid of SEQ ID NO:29.

[4] The technical feature linking groups I-CCXXXIV is a polynucleotide. The inventions listed as Groups I-DXCVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure. Although the polypeptides of Groups I-XIII, the polynucleotides of Groups XIV-XXVI, the polynucleotides of the transgenic organisms of Groups XXVII-XXXIX, and the antibodies of Groups XL-LII share a common property or activity, the compounds are not regarded as being of similar nature because all alternatives do not share a common structure.

- According to PCT Rule 13.2 unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The nucleic acids of Groups XIV-XXVI, the polypeptides of Groups I-XIII, the transgenic organisms of Groups XXVII-XXXIX, and the antibodies of Groups XL-LII share no special technical feature as the nucleic acids of Groups XIV-XXVI, particularly the nucleic acid of claim 12, encompasses nucleic acids that are not the same as the nucleic acid of the transgenic organism of Groups XXVII-XXXIX and do not correspond to the polypeptides of Groups I-XIII and instead encompass nucleic acids that encode polypeptides that do not elicit the antibodies of Groups XL-LII.

- According to PCT Rule 13.2 unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The

inventions of Groups I-CCXXXIV do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Groups I-XIII is a polypeptide, which is shown by Sigma Chemical Company 1993 Catalog to lack novelty or inventive step because Sigma Chemical Company 1993 Catalog teaches a biologically active fragment of SEQ ID NO:1, specifically a Gly-Gln dipeptide corresponding to amino acids 245-246 of SEQ ID NO:1 and does not make it a contribution over the prior art.

- 37 CFR 1.475 does not provide for the inclusion of multiple methods of use within the main invention. Accordingly, the methods of Groups LXVI-LXXVIII, CV-CXVII, CXLIV-CLVI, and CXCVI-CCXXI do not have unity of invention with the polypeptides of Groups I-XIII.

[5] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[6] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

[7] Claims 1-93 will be examined only to the extent the claims read on the elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.

Patent Examiner
Art Unit 1652

06-12-04